

What is claimed is:

1. A method for encapsulating and embedding a bioactive ingredient in mammalian newborn formulation comprising the steps of:
 - (i) mixing a bioactive ingredient with an encapsulating material herein said encapsulating material comprises food-grade materials and feed grade materials, either alone or in combination, forming a liquid blend,
 - (ii) drying of the liquid blend so as to form a dry blend, and
 - (iii) adding the dry blend to the mammalian newborn formulation, thereby encapsulating and embedding a bioactive ingredient in mammalian newborn formulation.
2. The method of claim 1, wherein the mammalian newborn food is infant formula
3. The method of claim 1, wherein the mammalian newborn food is a milk replacer
4. The method of claim 1, wherein the mammalian newborn food is a milk substitute.
5. The method of claim 1 further comprising the step of grinding the dry blend.
6. The method of claim 1, further comprising the step of mixing the dry blend with at least one additional encapsulating material wherein the at least one additional encapsulating material comprises food grade material and feed grade material, either alone or in combination.
7. The method of claim 1, wherein the mammalian newborn formulation is in the form of a powder, a solution, liquid, a spread, a semi-solid or a solid.
8. The method of claim 1, wherein the bioactive ingredient is insulin, IGF-I, IGF-II or EGF.

9. The method of claim 1, wherein the bioactive ingredient is a glycoprotein, immunoglobulin, peptide, polypeptide, hormone or enzyme.
10. The method of claim 1, wherein the bioactive ingredient is alpha-1 proteinase inhibitor, alkaline phosphatase, angiogenin, antithrombin III, chitinase, extracellular superoxide dismutase, Factor VIII, Factor IX, Factor X, fibrinogen, glucocerebrosidase, glutamate decarboxylase, human serum albumin, myelin basic protein, lactoferrin, lactoglobulin, lysozyme, lactalbumin, proinsulin, soluble CD4, component and complexes of soluble CD4, tissue plasminogen activator, pharmaceutically acceptable salt thereof, a combination thereof, an analog thereof and a variant thereof.
11. The method of claim 1 wherein the drying is performed by freeze drying, low temperature vacuum heat drying or low temperature spraying drying.
12. The method of claim 11, wherein said freeze-drying has an earlier step of freeze spraying.
13. The method of claim 11, wherein freeze spraying has an earlier step of extrusion.
14. The method of claim 1, wherein drying said liquid blend results in glassy freeze dried droplets containing a bioactive ingredient and at least one encapsulating material, wherein said encapsulating material is food grade material and feed grade material, either alone or in combination.
15. The method of claim 11, wherein said spray drying or said vacuum heat drying is conducted at a temperature which is below 50°C.
16. The method of claim 1, wherein the mammalian newborn formulation is for the consumption of the genera of, primate, bovine, porcine, ovine, canine, feline and caprine.

17. The method of claim 1, wherein the step of adding dry blend to the mammalian newborn formulation further include an earliest step for ensuring homogeneity.

18. The method of claim 1, wherein the food grade encapsulating material is maltodextrin.

19. The method of claim 1, wherein all of the ingredients are admixed together at a temperature below 50⁰C.

10 20. A method according to claim 1, wherein the encapsulating material is a solid.

21. A newborn edible formulation comprising a bioactive ingredient, said bioactive ingredient being encapsulated in an encapsulating material.

15 22. The newborn edible formulation of claim 21 wherein said encapsulating material further comprises at least one food grade material.

23. The newborn edible formulation of claim 21 wherein said encapsulating material further comprises at least one feed grade material.

20 24. The newborn formulation of claim 21, wherein said formulation is a human infant formula.

25 25. The newborn formula of claim 21, wherein said formulation is a milk replacer.

26. The newborn formulation of claim 21, wherein said formulation is a milk substitute.

30 27. The newborn formulation of claim 21, wherein the encapsulating material is polysaccharide, maltodextrin, milk powder, whey protein, lipid, gum Arabic or microcrystalline cellulose.

28. The newborn formulation of claim 21, wherein the bioactive ingredient maintains its biologically bioactive function and properties during processing of the newborn formulation.
- 5 29. The newborn formulation of claim 21, wherein the bioactive ingredient substantially maintains its biologically bioactive function and properties during processing of the newborn formulation.
- 10 30. The newborn formulation of claim 21, wherein the bioactive ingredient is insulin, IGF-I, IGF-2, or EGF
31. The newborn formulation of claim 21, wherein the formulation is in the form of a powder, a liquid, a solution, a spread, an ointment, semi-solid or solid.
- 15 32. The newborn formulation of claim 21, wherein if in a form of powder, the bioactive ingredient being encapsulated or embedded is released upon contact with a liquid.
- 20 33. The newborn formula of claim 21, wherein the bioactive ingredient is a glycoprotein, immunoglobulin, peptide, polypeptide, hormone or enzyme.
34. The newborn formula of claim 21, wherein the bioactive ingredient is alpha-1 proteinase inhibitor, alkaline phosphatase, angiogenin, antithrombin III, chitinase, extracellular superoxide dismutase, Factor VIII, Factor IX, Factor X, fibrinogen, glucocerebrosidase, glutamate decarboxylase, human serum albumin, myelin basic protein, lactoferrin, lactoglobulin, lysozyme, lactalbumin, proinsulin, soluble CD4, component and complexes of soluble CD4, tissue plasminogen activator and a variant thereof.
- 25 35. The newborn formulation of claim 21, comprising the bioactive ingredient being encapsulated or embedded in maltodextrin, milk powder, whey protein, lipid, Arabic gum or cellulose microcrystalline.

36. The newborn formulation of claim 21, comprises uniformly sized particles of encapsulated bioactive ingredient, wherein the particles have a radius between 1 microns and 1,000 microns

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37. A method for improving the health status of a mammal comprising the steps of administering to the mammal a newborn formulation according to claim 21, thereby being a method for improving the health status of a mammal.

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38. The method of claim 37, wherein said health status is growth or development of the mammal.

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39. A method of enriching a human infant formula, comprising admixing a bioactive ingredient into the human infant formula, said bioactive ingredient being encapsulated according to the method of claim 1, thereby being a method for enriching a human infant formula.

40. The method of claim 39, wherein the human infant formula is a milk replacer.

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41. The method of claim 39, wherein the human infant formula is a milk substitute

42. A method for encapsulating or embedding a bioactive ingredient in mammalian feed formulation comprising the steps of:

- (i) mixing the bioactive ingredient with encapsulating material;
- (ii) drying of the liquid blend;
- (iii) coating the dry blend with at least one additional encapsulating material layer; and
- (iv) adding the dry blend to the mammalian feed formulation;

Thereby encapsulating or embedding a bioactive ingredient in mammalian feed formulatio.

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43. The method of claim 42, wherein said at least one additional encapsulating material comprises food grade material, feed grade material either alone or in combination

5 44. The method of claim 42, wherein said feed formulation is solid or semi-solid.

45. The method of claim 42, wherein the feed formulation is in form of pellets or mesh, either alone or in combination.

10 46. The method of claim 42, further comprising grinding the dry blend.

47. The method of claim 42, further comprising grinding the coated dry blend

15 48. The method of claim 42, wherein the bioactive ingredient is insulin, IGF-I, IGF-II or EGF.

49. The method of claim 42, wherein the bioactive ingredient is a glycoprotein, immunoglobulin, peptide, polypeptide, hormone or enzyme.

20 50. The method of claim 42, wherein the the bioactive ingredient is alpha-1 proteinase inhibitor, alkaline phosphatase, angiogenin, antithrombin III, chitinase, extracellular superoxide dismutase, Factor VIII, Factor IX, Factor X, fibrinogen, glucocerebrosidase, glutamate decarboxylase, human serum albumin, myelin basic protein, lactoferrin, lactoglobulin, lysozyme, lactalbumin, proinsulin, soluble CD4, component and complexes of soluble CD4, tissue plasminogen activator and a variant thereof.

25 51. The method of claim 42 wherein the drying is performed by a process that is freeze drying, low temperature vaccum heat drying or low temperature spray drying.

52. The method of claim 42, wherein said freeze drying has an earlier step of freeze spraying.

5 53. The method of claim 51, wherein the process is carried out at a maximum temperature of 50°C.

10 54. The method of claim 42, wherein the mammalian feed formulation is for the consumption of genera that is primate, bovine, porcine, ovine, canine, feline and caprine.

15 55. The method of claim 42, wherein adding dry blend to the mammalian feed formulation further include premixing the blend in a small volume of the mammalian newborn feed.

56. The method of claim 42, wherein the encapsulating material is maltodextrin.

57. The method of claim 42, wherein all temperature not higher than 50 deg. C.

20 58. A method as claimed in claim 42, wherein the encapsulant is a solid.

59. A mammalian feed formulation, comprising a bioactive ingredient.

25 60. The feed formulation of claim 59, wherein said formulation is solid or semi-solid.

61. The feed formulation of claim 59, wherein said bioactive material is encapsulated in an encapsulating material

30 62. The feed formulation of claim 61, wherein the encapsulating material is food grade, feed grade, either alone or in combination.

63. The mammalian feed formulation of claim 59, wherein said formulation is in a form of a mash or pellets.

5 64. The mammalian feed formulation of claim 62, wherein the encapsulating material is polysaccharide, maltodextrin, milk powder, whey protein, lipid, gum Arabic, microcrystalline cellulose, alone or in combination thereof.

10 65. The mammalian feed formulation of claim 62, wherein the bioactive ingredient maintains its biological function during the processing of said feed formulation.

15 66. The mammalian feed formulation of claim 62, wherein the bioactive ingredient substantially maintains its biological activity during the processing of said feed formulation.

67. The mammalian feed formulation of claim 59, wherein the bioactive ingredient is insulin, IGF-1, IGF-2, EGF, either alone or in combination thereof.

20 68. The mammalian feed formulation of claim 59, wherein the bioactive ingredient is released upon contact with a liquid.

69. The mammalian feed formulation of claim 59, wherein the protein is a glycoprotein, immunoglobulin, peptide, polypeptide, hormone, enzyme, a pharmaceutically acceptable salt thereof, either alone or in combination.

25 70. The mammalian feed formulation of claim 59, wherein the bioactive ingredient is alpha-1 proteinase inhibitor, alkaline phosphatase, angiogenin, antithrombin III, chitinase, extracellular superoxide dismutase, Factor VIII, Factor IX, Factor X, fibrinogen, glucocerebrosidase, glutamate decarboxylase, human serum albumin, myelin basic protein, lactoferrin, lactoglobulin, lysozyme, lactalbumin, proinsulin, soluble CD4, component and complexes of soluble CD4, tissue plasminogen activator, a variant thereof, a pharmaceutically acceptable salt thereof, either alone or in combination..

71. The mammalian feed formulation of claim 64, wherein the encapsulating material is maltodextrin.
- 5 72. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 10-5000 microns.
73. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 1 - 2500 microns.
- 10 74. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 50 and 1000 microns.
- 15 75. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 50-500 microns.
76. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 10 – 25 microns
- 20 77. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 25 – 50 microns
78. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 50 – 100 microns
- 25 79. The mammalian feed formulation of claim 60, wherein the encapsulated bioactive material has an average diameter of between 100 - 500 microns
80. A method for improving the health status, of a mammal comprising administering to said mammal feed formulation according to claim 59.

81. The method of claim 80, wherein said health status is growth or development of the mammal.
- 5 82. A method of enriching mammalian feed formulation, comprising admixing into the mammalian feed formulation a bioactive ingredient according to the method of claim 59.
83. The feed formulation of claim 59 wherein the bioactive material is added as an emulsion.
- 10 84. The feed formulation of claim 83, wherein the emulsion is nano-emulsion.
85. The feed formulation of claim 83, wherein the emulsion is microemulsion.
- 15 86. A means for protecting bioactive materials in mammalian feed formulations.
87. A step for protecting bioactive materials in mammalian feed formulation.